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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/813,323	03/10/1997	DAVID BALTIMORE	50659/JPW/JM	3314

7590            06/03/2003

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[REDACTED] ART UNIT    [REDACTED] PAPER NUMBER

1642

DATE MAILED: 06/03/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicant No.</b>	<b>Applicant(s)</b>
	08/813,323	BALTIMORE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	MINH-TAM DAVIS	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 04 April 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 93 and 94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 93-94 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly claims 93-94 are examined in the instant application.

### **REJECTION UNDER 35 USC 112, SECOND PARAGRAPH**

Claims 93-94 remain rejected under 35 USC 112 second paragraph, pertaining to the size of the claimed consecutive amino acids, for reasons already of record in paper No:31.

Applicant argues that the claimed protein in claim 93 consists of consecutive amino acids extending between two defined residues, the sequence of which is set forth in SEQ ID NO:2, and thus the claimed protein cannot have any length, nor any structure. Applicant further asserts that the claimed protein extends from a proline corresponding to the proline at position 568 of SEQ ID NO:2 to a glycine corresponding to the glycine at position 416 of SEQ ID NO:2, thus defining the size of the consecutive amino acids.

Applicant argues that the claimed protein in claim 94 consists of consecutive amino acids, the sequence of which amino acid is included in the sequence set forth in SEQ ID NO:1. Applicant argues that the sequence of the claimed proteins must be included in the sequence set forth in SEQ ID NO:1, and that this necessarily characterizes both sequence and the length of the claimed protein.

Applicant's arguments in paper No: 32 have been considered but are found not to be persuasive for the following reasons:

Concerning claim 93, Applicant argues limitation not in the claim. Claim 93 does not recite the limitation of "consisting of consecutive amino acids extending between two defined residues, the sequence of which is set forth in SEQ ID NO:2." It is noted that due to the language "the sequence of which amino acid is included within the sequence set forth in SEQ ID NO: 2", the claimed protein could have any length and any structure, provided part of the sequence of which is the same as that of SEQ ID NO:2. Further, due to the language "corresponding", the protein of claim 93 needs only to have two amino acids, proline and glycine, at any position, since said protein would have amino acids proline and glycine "corresponding" to proline at position 568 of SEQ ID NO:2 at its carboxy terminus, and glycine at position 416 of SEQ ID NO:2, respectively.

Similar reasons for rejection apply for SEQ ID NO:1 of claim 94.

The claim language is confusing. Given Applicant's arguments, it appears that Applicant may be claiming a polypeptide consisting of the amino acids 415-567 of SEQ ID NO:1 or the amino acids 416-568 of SEQ ID NO:2. If this is in fact the scope of the claimed invention, Applicant might consider clarifying the claims. The Examiner would be willing to consider claims submitted after final if they are drawn to, for example, for claim 93, a polypeptide consisting of the amino acids 416-568 of SEQ ID NO:2, and for claim 94, a polypeptide consisting of the amino acids 415-567 of SEQ ID NO:1.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claims 93-94 remain rejected under 35 USC 112 second paragraph, pertaining to lack of a clear written description of the claimed proteins, for reasons already of record in paper No:31.

Applicant argues that a sequence consisting of two amino acids, proline and glycine, is not set forth in SEQ ID NO:2. Applicant further argues that the claimed protein cannot have any length, because the claimed protein consists of consecutive amino acids extending between the two defined residues, "the sequence of which is set forth in SEQ ID NO:2", as cited in claim 93. Applicant further asserts that the claimed protein cannot have any structure, because claim 93 characterizes the claimed protein as consisting of consecutive amino acids, the sequence of which is set forth in SEQ ID NO:2.

Applicant argues that claim 94 has been amended to recite a protein consisting of consecutive amino acids, the sequence of which must included in the sequence set forth in SEQ ID NO:1.

Applicant's arguments in paper No: 32 have been considered but are found not to be persuasive for the following reasons:

Concerning claim 93, Applicant argues limitation not in the claim. Claim 93 does not recite protein consists of consecutive amino acids "extending between the two defined residues", "the sequence of which is set forth in SEQ ID NO:2". It is noted that due to the language "the sequence of which amino acid is included within the sequence set forth in SEQ ID NO: 2", the claimed protein could have any length and any structure, provided part of the sequence of which is the same as that of SEQ ID NO:2. There is no

limitation in the claim of the size of the sequence which has to be included in SEQ ID NO:2.

Further, due to the language “corresponding”, the protein of claim 93 needs only to have two amino acids, proline and glycine, at any position, since said protein would have amino acids proline and glycine “corresponding” to proline at position 568 of SEQ ID NO:2 at its carboxy terminus, and glycine at position 416 of SEQ ID NO:2, respectively.

Similar reasons for rejection apply for SEQ ID NO:1 of claim 94.

The claim language is confusing. Given Applicant's arguments, it appears that Applicant may be claiming a polypeptide consisting of the amino acids 415-567 of SEQ ID NO:1 or the amino acids 416-568 of SEQ ID NO:2. If this is in fact the scope of the claimed invention, Applicant might consider clarifying the claims. The Examiner would be willing to consider claims submitted after final if they are drawn to, for example, for claim 93, a polypeptide consisting of the amino acids 416-568 of SEQ ID NO:2, and for claim 94, a polypeptide consisting of the amino acids 415-567 of SEQ ID NO:1.

#### **REJECTION UNDER 35 USC 102(b)**

Claims 93-94 remain rejected under 35 USC 102(b), pertaining to anticipation by Sato et al, for reasons already of record in paper No:31.

Applicant argues that concerning claim 93, the amino acid sequence of Sato et al has 181 amino acids, which extends from a proline at equivalent position 568 of SEQ ID NO:2 to well beyond the glycine corresponding to the glycine at position 416 of SEQ ID

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NO:2. Applicant asserts that the polypeptide disclosed by Sato et al does not consist of a sequence set forth in SEQ ID NO:2, which sequence extends from proline at position 568 of SEQ ID NO:2 at its carboxy terminus, and glycine at position 416 of SEQ ID NO:2.

Applicant further asserts that concerning claim 94, none of the polypeptides disclosed by Sato et al consists of consecutive amino acids having a sequence included in the sequence set forth in SEQ ID NO:1.

Applicant's arguments in paper No: 32 have been considered but are found not to be persuasive for the following reasons:

The limitation of a protein consisting of a sequence "set forth" in SEQ ID NO:2, "which sequence extends from proline at position 568 of SEQ ID NO:2 at its carboxy terminus, and glycine at position 416 of SEQ ID NO:2" is not in the claim 93. Thus Applicant argues limitation not in the claim.

Further, it is noted that due to the language "the sequence of which amino acid is included within the sequence set forth in SEQ ID NO: 2", the claimed protein of claim 93 could have any length and any structure, provided part of the sequence of which is the same as that of SEQ ID NO:2. There is no limitation in the claim of the size of the sequence which has to be included in SEQ ID NO:2.

Similar reasons for rejection apply for SEQ ID NO:1 of claim 94.

Thus the sequence taught by Sato et al seems to be the same as the claimed sequences in claims 93-94.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

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MINH TAM DAVIS

May 30, 2003

SUSAN UNGAR, PhD  
PRIMARY EXAMINER